

REMARKS

Claims 8 and 10-13 are pending. Claims 8 and 10-13 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Lieberman in view of Ullman and Geller. To the extent the instant Office Action repeats the obviousness rejection recited in the July 15, 2010 Office Action, applicants' September 1, 2010 Reply is incorporated herein by reference in its entirety.

A Request for Continued Examination (RCE) and the appropriate fee accompany this Reply.

Reconsideration is respectfully requested in view of the further amendments to the claims submitted in this Reply.

Lieberman was cited as teaching a pharmaceutical tablet with three layers wherein the center layer is free of active. Lieberman was also cited as teaching that it is known to place scores on tablets to allow for manual breakage. The Office Action acknowledges that Lieberman fails to "directly teach" a tablet with only two layers. In addition, Lieberman fails to teach or suggest making a bi-layer tablet having a single active layer and a single inactive layer, as claimed. Lieberman further fails to teach or suggest that the three-layer tablet, as described, can or should be modified by removing one of the active layers from the Lieberman three-layer tablet to arrive at a bi-layer tablet.

It is respectfully submitted that a person of ordinary skill in the tablet manufacturing art would not be directed toward making a three-layer tablet according to Lieberman (where the inactive layer is provided between two active layers solely to separate incompatible actives or compositions having different release profiles), then removing one of those active layers to arrive at a two-layered tablet with only one active layer and one inactive layer which advantageously provides integrity to the tablet during manufacture, shipping and handling, and, further, concomitantly facilitates accurate dose splitting following tablet division through the score. It is not enough to realize, based on the applicants' own disclosure, that a tablet according to Lieberman *could be* modified to arrive at the claimed invention. There must be some motivation in the prior art to carry out such modification since it would have been counterintuitive to first make a three-layer tablet, and then remove an active layer. Applicants maintain that no such motivation in the prior art is provided.

Applicants therefore respectfully submit that Lieberman in no way describes or suggests the claimed two-layer tablet, and fails to provide a basis for combining the secondary references therewith to present an obviousness rejection of the subject invention.

The secondary reference of Ullman is cited as teaching a multi-fractionable unitary structure. No contention has been raised that Ullman in any way teaches or suggests a two layered tablet because Ullman discloses only a single layer or homogeneous tablet structure. Accordingly, Ullman is believed to be inapposite to the claimed, layered-tablet invention. Even if properly cited, Ullman fails to cure the defects of Lieberman because Ullman does not teach or suggest a bi-layer tablet, nor does Ullman teach or suggest a bi-layer tablet consisting of a single inactive layer and a single active layer.

The secondary reference of Geller is applied as teaching deeply scored tablets (up to 66% of the entire tablet) having isosorbide as the active ingredient. The Office Action noted that Geller acknowledged the known deficiency of scored tablets, i.e., that "scores do not always assure precise division of the tablet". It should be noted that Geller, while acknowledging the problem of imprecise tablet splitting, does not suggest any solution to this imprecise tablet-splitting defect exhibited when breaking or splitting scored tablets. Geller especially fails to teach or suggest providing in a bi-layer tablet a second inert or inactive layer, as claimed, to address the problem of imprecise tablet splitting.

Therefore, it is clear that, because the secondary references of Ullman and Geller fail to cure the defects of the primary reference of Lieberman, the references taken together do not teach or suggest the claimed invention. Accordingly, the claimed invention, reciting a bi-layer tablet having one active layer and one inactive layer, which provides the unexpected advantage of precise dose-splitting, is believed to be unobvious in view of any one of the cited references, separately or combined.

Reconsideration and withdrawal of the rejection under 35 USC 103(a) is respectfully requested.

Finally, claims 8, and 10-12 were provisionally rejected for obviousness-type double patenting over co-pending application Serial No. 10/598,355.

A terminal disclaimer will be filed upon the indication of allowable subject matter to obviate the provisional double patenting rejection.

Applicants believe the subject claims, as amended, are now in condition for allowance, and respectfully request that a Notice of Allowance be issued for the instant application.

Should further information or clarification be required on any of these matters, applicants invite the Examiner to contact the undersigned at the address or phone/fax number provided below.

Respectfully submitted,

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